PB-216 486

NATIONAL SHELLFISH SANITATION PROGRAM MANUAL OF OPERATIONS. PART I: SANITATION OF SHELLFISH GROWING AREAS

Leroy S. Houser

Public Health Service
Washington, D. C.

1965

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5285 Port Royal Road, Springfield Va. 22151

PB 216 486

National Shellfish Sanitation Program

Manual of Operations

Part I

Sanitation of Shellfish Growing Areas

1965 Revision

Edited by

Leroy S. Houser, Sanitarian Director

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NATIONAL TECHNICAL
INFORMATION SERVICE
U S Department of Commerce
Springfield VA 22151

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Division of Environmental Engineering and Food Protection
Shellfish Sanitation Branch
Washington, D.C. 20201

I

This is part I of two companion volumes published by the Public Health Service with titles and publication numbers as follows:

National Shellfish Sanitation Program

Public Health Service Publication No. 33
(Revised 1965) Part I—Sanitation of
Shellfish Growing Areas

Public Health Service Publication No. 33
(Revised 1965) Part II—Sanitation of the
Harvesting and Processing of Shellfish

This is a revised edition published previously under the title: Cooperative Program for the Certification of Interstate Shellfish Shippers, Part I, Sanitation of Shellfish Growing Areas, 1962 Revision.

PUBLIC HEALTH SERVICE PUBLICATION NO. 33
Part I — Revised 1965

II

LIST OF PREVIOUS EDITIONS OF MANUAL OF OPERATIONS FOR NATIONAL SHELLFISH SANITATION PROGRAM—NOW SUPERSEDED

1925. Supplement No. 53 to Public Health Reports November 6, 1925 "Report of Committee on Sanitary Control of the Shellfish Industry in the United States".

1937. U.S. Public Health Service Minimum Requirements for Approval of State Shellfish Control Measures and Certification for Shippers in Interstate Commerce (Revised October 1937).

1946. Manual of Recommended Practice for Sanitary Control of the Shellfish Industry Recommended by the U.S. Public Health Service (Public Health Bulletin No. 295).

1957. Manual of Recommended Practice for Sanitary Control of the Shellfish Industry (Part II: Sanitation of the Harvesting and Processing of Shellfish). Printed as Part II of Public Health Service Publication No. 33.

1959. Manual of Recommended Practice for Sanitary Control of the Shellfish Industry (Part I: Sanitation of Shellfish Growing Areas). Printed as Part I of Public Health Service Publication No. 33.

1962. Cooperative Program for the Certification of Interstate Shellfish Shippers, Part II, Sanitation of the Harvesting and Processing of Shellfish. (Printed as Part II of Public Health Service Publication No. 33.)

1962. Cooperative Program for the Certification of Interstate Shellfish Shippers, Part I, Sanitation of Shellfish Growing Areas. (Printed as Part I of Public Health Service Publication No. 33.)

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FOREWORD

A Declaration of Principles

The National Shellfish Sanitation Program is an unusual teaming of State and Federal resources to preserve and manage a natural resource for a beneficial use. Although the current program is of comparatively recent origin, its development can be traced back through several centuries of American history. When the European colonists arrived they found almost unimagined natural wealth. Forests, rich agricultural land, minerals, and space itself, were present in quantities and a variety previously unknown. To these settlers one of the most valuable and readily useable of these natural resources was the food resources of the sea, particularly the estuaries. It is not surprising that shellfish were foremost among their staple food items.

The value of these renewable natural resources to the early settlers was reflected in colonial legislation designed to encourage their wise use. In 1658—over 300 years ago—the Dutch council of New Amsterdam passed an ordinance regulating the taking of oysters from the East River. Other early legislation, including that of New York (1715), New Jersey (1730), and Rhode Island (1734), was designed to regulate harvesting, presumably as conservative measures to guarantee a continuing supply.

The public health problems which were associated with shellfish in the United States in the first two decades of the present century brought a new dimension to natural resource utilization; i.e., shellfish could not be used for food unless of acceptable sanitary quality. This concept was clearly recognized in the Public Health Service sponsored conference of 1925 in which the concepts of the present cooperative program were first outlined and the administrative foundation put down. All parties seemed to recognize, and accept as fact, the premises that: (1) shellfish represented a valuable natural food resource; (2) the cultivation, harvesting, and marketing of this food resource were valuable components in the financial bases of many coastal communities; (3) a State and Federal program was necessary to permit the safe use of this resource; and (4) the transmission of disease by shellfish was preventable and therefore not to be tolerated. It is significant that the founders of this program did not take the parochial stand that the only completely safe way to prevent disease transmission by shellfish was to prohibit its use. Instead, they held that this beneficial use of the estuaries was in the best public interest, and that sanitary controls should be developed and maintained which would allow safe use. These concepts were recognized in the program which evolved following the report of the "Committee on Sanitary Control of the Shellfish Industry in the United States" in 1925.

In 1954 the Surgeon General of the U.S. Public Health Service called a second national conference to discuss shellfish sanitation problems. Specifically, the 1954 conference addressed itself to the questions of the practicality and need for this tripartite program. There was general agreement that, despite the profusion of technical problems, the basic concepts were sound and that it was in the public interest to maintain the program. Thus, the presence of an irrevocable bond between the application of sanitary controls in the shellfish industry and the continuing beneficial use of a renewable natural resource was again confirmed.

Despite this long established relationship the national program has tended to neglect the second of these biphasic goals—use of a valuable natural resource—and to concentrate on the negative policy of closure of areas of unsuitable sanitary quality. Little effort has been made by the program to develop a compensatory ele-

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ment which would encourage corrective action by State or Federal agencies. Similarly, the program has not taken a position on the use of conservation law even when it was known that this would increase the program's consumer protection confidence factor.

In recognition of past history of the shellfish industry in the United States and of the relationship of the National Shellfish Sanitation Program to the effective use of this natural resource, the 1964 Shellfish Sanitation Workshop endorses the following principles:

1. Shellfish are a renewable, manageable natural resource of significant economical value to many coastal communities, and which should be managed as carefully as are other natural resources such as forests, water, and agricultural lands.
2. Shellfish culture and harvesting represents a beneficial use of water in the estuaries. This use should be recognized by State and Federal agencies in planning and carrying out pollution prevention and abatement programs and in comprehensive planning for the use of these areas.
3. The goals of the National Shellfish Sanitation Program are: (1) the continued safe use of this natural resource and (2) active encouragement of water quality programs which will preserve all possible coastal areas for this beneficial use.

It is the conviction of the 1964 National Shellfish Sanitation Workshop that survival of the shellfish industry is in the best public interest; that by application of the above principles on a State-by-State basis shellfish can continue to be used safely as food and to make a valuable contribution to the economic structure of the Nation both in the immediate present and in the foreseeable future.

Introduction

In 1925 State and local health authorities and representatives of the shellfish industry requested the Public Health Service to exercise supervision over the sanitary quality of shellfish shipped in interstate commerce. In accordance with this request, a cooperative control procedure was developed. In carrying out this cooperative control, the States, the shellfish industry, and the Public Health Service, each accept responsibility for certain procedures as follows.

1. Procedures To Be Followed by the State.—Each shellfish-shipping State adopts adequate laws and regulations for sanitary control of the shellfish industry, makes sanitary and bacteriological surveys of growing areas, delineates and patrols restricted areas, inspects shellfish plants, and conducts such additional inspections, laboratory investigations, and control measures as may be necessary to insure that the shellfish reaching the consumer have been grown, harvested, and processed in a sanitary manner. The State annually issues numbered certificates to shellfish dealers who comply with the agreed-upon sanitary standards, and forwards copies of the interstate certificates to the Public Health Service.

2. Procedures To Be Followed by the Public Health Service.—The Public Health Service makes an annual review of each State's control program including the inspection of a representative number of shellfish-processing plants. On the basis of the information thus obtained, the Public Health Service either endorses or withholds endorsement of the respective State control programs. For the information of health authorities and others concerned, the Public Health Service publishes a semimonthly list of all valid interstate shellfish-shipper certificates issued by the State shellfish-control authorities.

3. Procedures To Be Followed by the Industry.—The shellfish industry cooperates by obtaining shellfish from safe sources, by providing plants which meet the agreed-upon sanitary standards, by maintaining sanitary plant conditions, by placing the proper certificate number on each package of shellfish, and by keeping and making available to the control authorities records which show the origin and disposition of all shellfish.

The fundamental components of this National Shellfish Sanitation Program were first described in a *Supplement to Public Health Reports*, "Report of Committee on Sanitary Control of the Shellfish Industry in the United States" (1925). This guide for sanitary control of the shellfish industry was revised and reissued in 1937 and again in 1946. It was separated into two parts by publication of Part II, Sanitation of the Harvesting and Processing of Shellfish in 1957 and by publication in 1959, of Part I, Sanitation of Shellfish Growing Areas. The need for a specialized program of this nature was reaffirmed at the National Conference on Shellfish Sanitation held in Washington, D.C., in 1954 (*1*) and at the Shellfish Sanitation Workshop held in 1956 (*2*), 1958 (*3*), 1961 (*67*) and 1964 (*68*).

This edition of the shellfish sanitation manual has been prepared in cooperation with the State shellfish control authorities in all coastal States, food control authorities in the inland States, interested Federal agencies, Canadian Federal departments, the Oyster Institute of North America, the Pacific Coast Oyster Growers Association, and the Oyster Growers and Dealers Association of North America.

Since the growing and processing of shellfish are two distinct phases of operation in the shellfish industry, the manual has been prepared in two parts: I: Sanitation of Shellfish-Growing Areas; and II: Sanitation of the Harvesting and Processing of Shellfish. This, Part I of the manual, is intended as a guide for the preparation of State shellfish sanitation laws and regulations, and for sanitary control of the growing, relaying, and purification of shellfish. It is in-

tended that States participating in the National Shellfish Sanitation program for the certification of interstate shellfish shippers will be guided by this manual in exercising sanitary supervision over shellfish growing, relaying, and purification, and in the issuing of certificates to shellfish shippers.

The manual will also be used by the Public Health Service in evaluating State shellfish sanitation programs to determine if the programs qualify for endorsement. Part III of the manual, "Public Health Service Appraisal of State Shellfish Sanitation Programs", sets forth appraisal procedures in evaluating State shellfish sanitation programs and is based on the requirements contained in parts I and II.

The provisions of this manual were accepted at the Shellfish Sanitation Workshop held in Washington, November 17–19, 1964, and unless otherwise stated become effective 60 days after publication (*68*).

EUGENE T. JENSEN,
Chief, Shellfish Sanitation Branch, Division of Environmental Engineering and Food Protection, Public Health Service.

Definitions

And/or.—Where this term is used, *and* shall apply where possible; otherwise, *or* shall apply.

Area, growing.—An area in which market shellfish are grown.

Coliform group.—The coliform group includes all of the aerobic and facultative anaerobic, Gram-negtative, non-spore-forming bacilli which ferment lactose with gas formation within 48 hours at 35° C. Bacteria of this group which will produce gas from E. C. medium within 24 hours at 44.5° C. in a water bath will be referred to as fecal coliforms.

Controlled purification.—The process of removing contamination from whole live shellfish acquired while growing in polluted areas.

National shellfish sanitation program.—The cooperative State-PHS-Industry program for the certification of interstate shellfish shippers as described in Public Health Service Publication Number 33, *National Shellfish Sanitation Program Manual of Operations*, Parts I and II.

Depletion.—The removal of all market-size shellfish from an area.

Most probable number (abbreviated MPN).—The MPN is a statistical estimate of the number of bacteria per unit volume, and is determined from the number of positive results in a series of fermentation tubes. A complete discussion of MPN determinations and computations, including MPN tables, can be found in the American Public Health Association publication "Standard Methods for the Examination of Water and Waste Water" (*4*) (*5*).

Population equivalent (coliform).—A quantity of sewage containing approximately 160×10^9 coliform group bacteria. This is approximately equal to the per capita per day contribution of coliforms as determined in a metropolitan sewerage system (*6*) (*7*) (*8*).

Sanitary survey.—The sanitary survey is the evaluation of all factors having a bearing on the sanitary quality of a shellfish growing area including sources of pollution, the effects of wind, tides, and currents in the distribution and dilution of the polluting materials, and the bacteriological quality of the water.

Shellfish.—All edible species of oysters, clams, or mussels, either shucked or in the shell, fresh or frozen.

Shellfish, market.—Shellfish which are, may be, or have been harvested and/or prepared for sale for human consumption as a fresh or frozen product.

State shellfish control agency.—The State agency or agencies having legal authority to classify shellfish growing areas and/or to issue permits for the interstate shipment of shellfish in accord with the provisions of this manual.

State shellfish patrol agency.—The State agency having responsibility for the patrol of shellfish growing areas.

Transplanting.—The moving of shellfish from one area to another area.

Section A

GENERAL ADMINISTRATIVE PROCEDURES

I. State Laws and Regulations.—State laws or regulations shall provide an adequate legal basis for sanitary control of all interstate phases of the shellfish industry. This legal authority shall enable one or more departments or agencies of the State to classify all coastal waters for shellfish harvesting on the basis of sanitary quality; effectively regulate the harvesting of shellfish; effectively prosecute persons apprehended harvesting shellfish from restricted, prohibited, or nonapproved areas; regulate and supervise the shipment and storage of shell stock, and the shucking, packing, and repacking of shellfish; make laboratory examinations of shellfish; seize, condemn, or embargo shellfish; and restrict the harvesting of shellfish from particular areas and suspend interstate shipper certificates in public-health emergencies.

Satisfactory compliance.—This item will be satisfied when the State has legal authority to—

a. Classify all actual or potential shellfish growing areas as to their suitability for shellfish harvesting on the basis of sanitary quality as defined in section C of this manual. (It is strongly recommended that a State permit be required for the growing of shellfish, and that such permits be revocable or subject to suspension for just cause. It is also recommended that the State have authority to regulate the discharge of sewage, radioactive, and other toxic wastes from boats in the vicinity of approved shellfish growing areas.)

b. Control the harvesting of shellfish from areas which are contaminated or which contain marine shellfish poisons. To be effective this authority must allow the State to—

(1) Patrol growing areas.

(2) Apprehend persons violating the restrictions.

(3) Effectively prosecute persons apprehended harvesting shellfish from *restricted* or *prohibited* areas. (Penalties for such violations should be sufficient to discourage illegal harvesting.)

c. Regulate and supervise relaying, depletion, wet storage, and controlled purification as described in this manual if these techniques are used.

d. Require that shell stock in storage or in transit from the growing area to the certified shipper be protected against contamination; i.e., every person, firm, or corporation that handles shellfish up to the certified shipper will be subject to sanitary control by an official agency but will not necessarily be required to have a State shellfish permit.

e. Prohibit national program shippers from possessing or selling shellfish from out-of-State sources unless such shellfish have been produced in accord with cooperative program requirements.

f. Regulate the operations of shucker-packers, repackers, shell stock shippers and reshippers in accord with the applicable provisions of part II of this manual.

g. Restrict the harvesting of shellfish from specific areas, and suspend interstate shipper certificates in a public-health emergency. **Administrative procedures required in connection with such emergency actions should not require more than one day to complete.**

h. Prevent the sale, shipment, or possession of shellfish which cannot be identified as having been produced in accord with national program requirements or which are otherwise unfit for human consumption, and to condemn, seize, or embargo such shellfish. This authority need not be specific for shellfish and may be included in other State food laws.

Public-health explanation.—The National Program was developed by the 1925 Conference on Shellfish Pollution to meet the specific public-health need resulting from the 1924–25 typhoid epidemic (*9*).

However, the National Program has gone beyond the original objective of insuring that shellfish shipped interstate would not be the cause of communicable disease. Thus, in the 1940's, paralytic shellfish poison became a matter of public-health concern and steps were taken to protect the public against this hazard. In 1957 it was recognized that shellfish might concentrate certain radionuclides and that a

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radiation surveillance activity might become a necessary adjunct to the established procedures.

To accomplish these public-health objectives the State must supervise all phases of the growing, harvesting, transportation, shucking-packing, and repacking of shellfish to be shipped interstate. It is also important that shellfish be properly refrigerated and protected against contamination during interstate shipment. This is not easily accomplished by the State of origin although certified shippers are required to pack shellfish in containers which will protect them against contamination.

If State supervision is to be effective all phases of the activity must be supported by legal authority. This authority may be either a specific law or regulation. The success with which the State is able to regulate the several components of the shellfish industry provides a measure of the adequacy of the statutory authority.

The unique nature of shellfish as a food also makes it necessary that the State shellfish control agency have authority to take immediate emergency action to halt harvesting or processing of shellfish without recourse to lengthy administrative procedures. As examples, a State may find it necessary to close a shellfish growing area within hours of a breakdown in a sewage treatment plant or the unexpected finding of paralytic shellfish poison.

Periodic revisions of State shellfish laws or regulations may be necessary to cope with new public-health hazards and to reflect new knowledge. Examples of changes or developments which have called for revision of State laws include the wide-scale use of pleasure boats with the resulting probability of contamination of shellfish growing areas with fresh fecal material, the conditionally approved area concept resulting from the construction of sewage treatment works, and the apparent ability of shellfish to concentrate certain radionuclides.

Experience has demonstrated that all actual and potential shellfish growing waters of the State must be classified as to their sanitary suitability for shellfish harvesting. Harvesting should be permitted only from those areas which have been found by sanitary survey to meet the sanitary criteria of this manual. Harvesting should accordingly be specifically prohibited from areas which do not meet the criteria, or which have not been surveyed.

2. General Administrative Procedures To Be Used by States.—States shall keep records which will facilitate Public Health Service review of their shellfish sanitation programs and shall assist the Service in making such reviews. States shall not certify shippers for interstate shipment unless the shipper complies substantially with the construction requirements of part II of this manual and maintains a sanitation rating of at least 80 percent during periods of operation. Shippers not meeting these requirements will not be eligible for inclusion on the Public Health Service list of State-certified shellfish shippers. National Program standards shall be applied to all actual and potential growing areas, all shellfish harvesters, and all persons handling shell stock prior to its delivery to the national program certified shipper. When two or more State agencies are involved in the sanitary control of the shellfish industry, a clear statement of responsibility of each agency should be developed.

Satisfactory compliance.—This item will be satisfied when—

a. National Program requirements are applied to all actual and potential shellfish growing areas.

b. National Program requirements are applied to all commercial market shellfish harvesters.

c. National Program requirements are applied to all persons handling the shellfish prior to its delivery to the interstate shipper.

d. Interstate shellfish shipper certificates are issued only to those establishments substantially meeting the construction requirements of part II of this manual and which maintain a plant sanitation rating of at least 80 percent during periods of operations. (The State shellfish control agency shall suspend or revoke certificates if a plant sanitation rating drops below 80 percent or if any individual sanitation item is violated repeatedly.) Ratings will be determined on the basis of compliance with the applicable provisions of part II of this manual as measured by an inspection report comparable to that contained in appendix A of part II.

e. The following records are kept of shellfish sanitation activities as required in sections C,

D, and E, Part I, of this manual and when monthly summaries of State patrol activities are forwarded to the Public Health Service regional office:

(1) Individual growing area files. (Areas may be defined by either geographic or political boundaries.)

(2) Patrol activities, including arrests, prosecutions, and the results of prosecutions.

(3) Plant inspections. Shucker-packers and repackers shall ordinarily be inspected at least monthly. Shell stock shippers and reshippers shall be inspected at a frequency which will afford adequate public-health supervision of their operations. A central inspection-report file should be maintained by the State.

f. The following guidelines are observed by the State in issuing interstate shellfish certificates.

(1) Certificate content. Each certificate should give the following information:

Name. (The usual business name and alternative names that should appear on the interstate shellfish shippers list, hereafter called "list.")

Address. (A business and/or mailing address in the State issuing the certificate. This address indicates where records are kept and where inspection may be arranged.)

Certificate Number. (A number shall be assigned for each business unit. Suffix or prefix letters may not be used to differentiate between two or more plants of a given shipper.)

Classification. (The shipper classification should be indicated by a symbol: i.e., shucker-packer, SP; repacker, RP; shell stock, SS; or reshipper, RS. Only one classification should be used. The single classification will cover all proposed operations which the shipper is qualified to perform.)

Expiration Date. (All certificates in a State should expire on the same date, preferably the last day of a month. This date will be shown on the "list". All certificates will be automatically withdrawn from the "list" on the date of expiration unless new certificates have been received by Public Health Service headquarters office. If the date of expiration coincides with the date of issue for the "list" the certificates expiring on the date of issue will be deleted.)

Certifying Officer. (Each certificate is signed by a responsible State official.)

(2) Certificate changes. A change in an existing, unexpired certificate should be made by issuing a corrected certificate.

(3) Interstate shipment before listing. The shipper should be informed of the probable date his name will appear on the "list" and should be advised against making interstate shipment prior to that date. (If shipments must be made before the appearance of the shipper's name on the "list", the Public Health Service will notify the applicable receiving States if the names and addresses of the expected receivers are indicated in advance by the State when the certificate is forwarded to the Public Health Service.)

(4) State cancellation, revocation, or suspension of interstate shipper certificates. If a State revokes, cancels, or suspends an interstate shellfish shipper certificate, the Public Health Service regional office should be immediately notified, preferably by telephone or telegram, with a following confirmatory letter.

(5) Mailing list for interstate shellfish shipper list. Names of persons, business units, organizations, or agencies, desiring copies of the "list", and requests for information concerning the "list" should be sent to the appropriate Public Health Service regional office. Recipients will be circularized periodically to determine if they still have use for the "list".

g. The appropriate Public Health Service regional office is notified by the State of any revision in growing area classification. The notification shall so describe the area that it may be readily located on Coast and Geodetic Survey charts.

h. State shellfish plant inspectors are provided with the following inspection equipment: standardized inspection forms, thermometer, chlorine test kit, and light meter.

i. Interdepartmental memoranda of understanding have been developed which will define the responsibilities of each State agency in maintaining adequate sanitary control of the shellfish industry in the State.

Public-health explanation.—The annual review of each participating State's shellfish sanitation activities is a fundamental Public Health Service responsibility in the National Program. The purpose of this review is to evaluate the adequacy and reliability of each individual State program in accord with the agreed-upon standards. The Service will endorse those State programs meeting the National Program standards and will publish and distribute a list of the names of the State certified shippers. However, if a State program does not meet the standards the program will not be endorsed. Names of nonparticipating States will be omitted from the Public Health Service list of State certified shellfish shippers.

Minimum plant sanitation standards for interstate shellfish shippers are described in part II of this manual. Experience has shown that absolute compliance with these minimum standards is not always attainable, particularly those items which relate to operating procedures. The establishment of the 80-percent plant sanitation score as a prerequisite for listing on the Public Health Service list of State certified shellfish shippers recognizes the fact that perfection is not always obtainable and, at the same time, provides a mechanism for excluding any plant which is not operated in a reasonably sanitary manner.

National program sanitary requirements should be applied to all actual and potential growing areas and all shellfish harvesters to insure that all shellfish available to certified dealers have been produced and harvested under acceptable sanitary conditions. It is also important that the shell stock be protected against contamination during the period between harvesting and delivery to the certified shipper.

3. Intrastate Sale of Market Shellfish.—Sanitary standards for intrastate shellfish shippers should be substantially equivalent to those of the national program.

Public-health explanation.—States may accept lower sanitary standards for shellfish sold intrastate than are required by the National Program. However, it has been found that small intrastate shippers may at times sell their product to interstate shippers if demand exceeds the supply of shellfish available to the latter. Because of the possibility that such substandard shellfish might be shipped interstate, the 1954 National Conference on Shellfish Sanitation recommended that National Program standards be applied to all shellfish production and processing (*1*). The 1958 Shellfish Sanitation Workshop also strongly recommended the use of substantially equivalent standards for intra- and inter-state shellfish shippers (*3*).

Section B

LABORATORY PROCEDURES

1. Bacteriological.—American Public Health Association Recommended Procedures for the Examination of Sea Water and Shellfish shall be followed in the collection and transportation of samples of shellfish and shellfish waters for bacteriological examination and in the laboratory examination of such samples.[1]

Satisfactory compliance.—This item will be satisfied when current American Public Health Association Recommended Procedures for the Examination of Sea Water and Shellfish are followed in the bacteriological examination of shellfish and shellfish waters.

Public-health explanation.—Experience with the bacteriological examination of shellfish and shellfish growing waters has indicated that minor differences in laboratory procedures or techniques will cause wide variations in the results. Variations in results may also be caused by improper handling of the sample during collection or transportation to the laboratory (*10*). The American Public Health Association Recommended Procedures for the Examination of Sea Water and Shellfish, which are revised periodically, offer a reliable way of minimizing these variations (*62*). (National Program required use of a standard procedure for the bacteriological examination of shellfish and shellfish waters should not discourage laboratories from working on new methods of sample handling or analysis.)

2. Toxicological.—A recognized procedure shall be used in the assay for paralytic shellfish poison.

Satisfactory compliance.—This item will be satisfied when current Association of Official Agricultural Chemists official methods are followed in the bioassay for paralytic shellfish poison.

Public-health explanation.—It has been demonstrated that significant variations in bioassay results will be caused by minor changes in procedures. If reliable results are to be obtained it is essential that the test procedures be standardized and that variations due to use of strains of mice be minimized (*11*). The official procedure for the bioassay for paralytic shellfish poison adopted by the Association of Official Agricultural Chemists minimizes these variations (*66*). A method of analysis for ciguatera poison in shellfish has been developed (*12*).

3. Chemical and Physical.—Standard laboratory methods shall be used for all salinity, radionuclide, and other chemical and physical determinations made on shellfish or shellfish waters in conjunction with National Program activities. Results shall be reported in standard units.

Satisfactory compliance.—This item will be satisfied when—

a. Chemical and physical measurements on shellfish and shellfish waters are made in accord with accepted laboratory techniques.

b. Results of all chemical and physical determinations are expressed in standard units. (For example, salinity should be expressed in parts per thousand rather than hydrometer readings.)

Public-health explanation.—Standardized laboratory procedures are most apt to produce results in which the State shellfish control agency can have confidence, and facilitate comparative evaluation of data. The need for adherence to standardized procedures should not discourage laboratories from experimental use of nonstandard methods.

[1] Material which may be useful in interpretation of results of bacteriological examination of shellfish is contained in appendix A.

Section C

GROWING AREA SURVEY AND CLASSIFICATION

1. Sanitary Surveys of Growing Areas.—A sanitary survey shall be made of each growing area prior to its approval by the State as a source of market shellfish or of shellfish to be used in a controlled purification or relaying operation. The sanitary quality of each area shall be reappraised at least biennially and, if necessary, a resurvey made. Ordinarily, resurveys will be much less comprehensive than the original survey since it will only be necessary to bring the original information up to date. Records of all original surveys and resurveys of growing areas shall be maintained by the State shellfish control agency, and shall be made available to Public Health Service review officers upon request.

Satisfactory compliance.—This item will be satisfied when—

a. A sanitary survey has been made of each growing area in the State prior to initial approval of interstate shipments of shellfish from that area. A comprehensive sanitary survey shall include an evaluation of all sources of actual or potential pollution on the estuary and its tributaries, and the distance of such sources from the growing areas; effectiveness and reliability of sewage treatment works; the presence of industrial wastes, pesticides, or radionuclides which would cause a public-health hazard to the consumer of the shellfish; and the effect of wind, stream flow, and tidal currents in distributing polluting materials over the growing area.[2] The thoroughness with which each element must be investigated varies greatly and will be determined by the specific conditions in each growing area.

b. The factors influencing the sanitary quality of each approved shellfish growing area are reappraised at least biennially.[3] A complete resurvey should be made of each growing area in an approved category at least once every ten years; however, data from original surveys can be used when it is clear that such information is still valid.

c. A file which contains all pertinent sanitary survey information, including the dates and results of preceding sanitary surveys is maintained by the State shellfish control agency for each classified shellfish area.

d. The State agency having primary responsibility for this element of the national program develops a system for identification of growing areas.

Public-health explanation.—The positive relationship between sewage pollution of shellfish growing areas and enteric disease has been demonstrated many times (*13*) (*14*) (*15*) (*16*) (*17*) (*18*) (*63*) (*64*) (*65*). However, epidemiological investigations of shellfish-caused disease outbreaks have never established a direct numerical correlation between the bacteriological quality of water and the degree of hazard to health. Investigations made from 1914 to 1925 by the States and the Public Health Service—a period when disease outbreaks attributable to shellfish were more prevalent—indicated that typhoid fever or other enteric disease would not ordinarily be attributed to shellfish harvested from water in which not more than 50 percent of the 1 cc. portions of water examined were positive for coliforms,[4] *provided the areas were not subject to direct contamination with small amounts of fresh sewage which would not ordinarily be revealed by the bacteriological examination.*

Following the oyster-borne typhoid outbreak during the winter of 1924–25 in the United States (*19*) the national shellfish certification program was initiated by the States, the Public Health Service, and the shellfish industry (*9*). Water quality criteria were then stated as:

a. The area is sufficiently removed from major sources of pollution so that the shellfish would not be subjected to fecal contamination in quantities which might be dangerous to the public health.

[2] In making the sanitary survey consideration should be given to the hydrographic and geographic characteristics of the estuary, the bacteriological quality of the growing area water and bottom sediments, and the presence and location of small sources of pollution, including boats, which might contribute fresh sewage to the area.

[3] The purpose of this reappraisal is to determine if there have been changes in stream flow, sewage treatment, populations, or other similar factors which might result in a change in the sanitary quality of the growing area. The amount of field work associated with such a reappraisal will depend upon the area under consideration and the magnitude of the changes which have taken place.

[4] An MPN of approximately 70 per 100 ml.

b. The area is free from pollution by even small quantities of fresh sewage. The report emphasized that bacteriological examination does not, in itself, offer conclusive proof of the sanitary quality of an area.

c. Bacteriological examination does not ordinarily show the presence of the coli-aerogenes group of bacteria in 1 cc. dilutions of growing area water.

The reliability of this three-part standard for evaluating the safety of shellfish-producing areas is evidenced by the fact that no major outbreaks of typhoid fever or other enteric disease have been attributed to shellfish harvested from waters meeting the criteria since they were adopted in the United States in 1925. Similar water quality criteria have been in use in Canada with like results. The available epidemiological and laboratory evidence gives little idea as to the margin of safety, but it is probably considerable as indicated by the virtual absence of reported shellfish caused enteric disease over a comparatively long period of time (*18*) (*20*) (*21*) (*65*) (*69*) from waters meeting this criteria.

The purpose of the sanitary survey is to identify and evaluate those factors influencing the sanitary quality of a growing area and which may include sources of pollution, potential or actual; the volume of dilution water; the effects of currents, winds and tides in disseminating pollution over the growing areas; the bacterial quality of water and bottom sediments; die out of polluting bacteria in the tributaries and the estuary; bottom configuration; and salinity and turbidity of the water. Sources of pollution include municipal sewage discharged into the estuary or inflowing rivers; sewage brought into the estuary by tides or currents; surface runoff from polluted areas; industrial wastes; and discharges from pleasure craft, fishing boats, naval vessels, and merchant shipping.

Bacteriological examination of the growing waters is an important component of the sanitary survey. In many instances the bacteriological and related salinity data will also provide valuable information on the hydrographic characteristics of an area.[5] [6]

Ideally, a large number of water samples for bacteriological examination should be collected at each station. However, in most instances this is not practical because of time and budget limitations, and accordingly only a limited number of samples can be collected. Therefore, sampling stations should be chosen which will provide a maximum of data, and which will be respresentative of the bacteriological quality of water in as wide an area as possible. Sample collection should be timed to represent the most unfavorable hydrographic and pollution conditions since shellfish respond rapidly to an increase in the number of bacteria or viruses in their environment (*25*) (*26*) (*70*) (*71*) (*72*) (*78*).

There is no specified minimum number of sampling stations, frequency of sampling, or total number of samples. Sampling results obtained over a period of several years can be used as a block of data provided at least 15 samples have been collected from each of a representative number of stations along the line separating approved from restricted growing areas and there have been no adverse changes in hydrographic or sanitary conditions. Only occasional bacteriological samples are necessary from areas which are shown to be free from pollution.

Experience with the shellfish certification program indicates a tendency to omit or de-emphasize some components of the sanitary survey unless a central State file of all shellfish sanitary surveys, reappraisals, and resurveys is maintained. This is particularly true where responsibility for shellfish sanitation is divided between two or more State agencies. Maintenance of a central State file for all shellfish sanitary survey information will also simplify the endorsement appraisal of State programs by the Public Health Service and will help prevent

[5] Bacteria in an unfavorable environment die out in such a way that following an initial lag period there is a large percentage decline during the first few days. Descriptions of studies on bacteria dieout have been published by Greenberg (*22*) and Pearson (*23*). Dieoff has also been investigated by the Public Health Service Shellfish Sanitation Laboratory at Woods Hole, Mass., and Pensacola, Fla. Application of this principle may be helpful in predicting the quantity of pollution which will reach an area, and in establishing objective effluent quality criteria (*24*).

[6] In connection with the evaluation of sampling results, it should be noted that the MPN determination is not a precise measure of the concentration of bacteria (*4*). Thus, in repeated sampling from waters having a uniform density of bacteria varying MPN estimates will be obtained. The use of the tolerance factor 3.3 (applicable only to 5 tube decimal dilution MPN's) is one method of recognizing this variation. For example, in a body of water in which the median concentration of coliform bacteria is 70 per 100 ml., 95% of observed MPN's will be between 20 and 230 per 100 ml.; i.e., $70/3.3=21$ and $70\times3.3=230$.

loss of old data which may be useful in evaluating the sanitary quality of an area.

Periodic reappraisals of the sanitary quality of shellfish producing areas are necessary to determine that environmental conditions are such that the original conclusions are still valid. A *resurvey* should be made within 1 year if the *reappraisal* shows a significant detrimental change.

2. Classification of Growing Areas.—All actual and potential growing waters shall be classified as to their public health suitability for the harvesting of market shellfish. Classification criteria are described in sections C–3, C–4, C–5, C–6, and C–7 of this manual. Except in emergency any upward revision of an area classification shall be preceded by a sanitary survey, resurvey, or reappraisal. A written anaiysis of the data justifying the reclassification shall be made a part of the area file.

Satisfactory compliance.—This item will be satisfied when—

a. All actual and potential growing waters in the State are correctly designated with one of the following classifications on the basis of sanitary survey information: *Approved; conditionally approved; restricted;* or *prohibited.*[7] *

b. Area classifications are revised whenever warranted by survey data.

c. Classifications are not revised upward without at least a file review, and there is a written record of such review in the area file maintained by the State shellfish control agency.

d. All actual and potential growing areas which have not been subjected to sanitary surveys shall be automatically classified as *prohibited.*

Public-health explanation.—The probable presence or absence of pathogenic organisms in shellfish waters is of the greatest importance in deciding how shellfish obtained from an area may be used. All actual and potential growing waters should thus be classified according to the information developed in the sanitary survey. Classification should not be revised upward without careful consideration of available data. Areas should be reclassified whenever warranted by existing data. A written justification for the reclassification simplifies Public Health Service appraisal of State programs.

A hypothetical use of the four recognized area classifications is shown in figure 1. This idealized situation depicts an estuary receiving sewage from two cities, "A" and "B." City "A" has complete sewage treatment including chlorination of effluent. City "B" has no sewage treatment. The estuary has been divided into five areas, designated by roman numerals, on the basis of sanitary survey information:

Approved

Area I. The sanitary survey indicates that sewage from cities "A" and "B" (even with the "A" sewage plant not functioning) would not reach this area in such concentration as to constitute a public-health hazard. The median coliform MPN of the water is less than 70/100 ml. The sanitary quality of the area is independent of sewage treatment at city "A."

Conditionally Approved

Area II. This area is of the same sanitary quality as area I: however, the quality varies with the effectiveness of sewage treatment at city "A." This area would probably be classified *prohibited* if city "A" had not provided sewage treatment.

Restricted

Area III. Sewage from "B" reaches this area, and the median coliform MPN of water is between 70 and 700 per 100 ml. Shellfish may be used only under specified conditions.

Prohibited

Area IV. Direct harvesting from this area is prohibited because of raw sewage from "B." The median coliform MPN of water may exceed 700/100 ml.

Area V. Direct harvesting from this area is prohibited because of possible failure of the sewage treatment plant. Closure is based on need for a safety factor rather than coliform content of water or amount of dilution water.

[7] Closures may also be based on presence of Marine Toxins or other toxic materials.

*States may use other terminology in describing area classifications; provided, that the classification terms used are consistent with the intent and meaning of the words "approved", "conditionally approved", "restricted", or "prohibited".

3. Approved Areas.—Growing areas may be designated as *approved* when: (*a*) the sanitary survey indicates that pathogenic microorganisms, radionuclides, and/or harmful industrial wastes do not reach the area in dangerous concentration, and (*b*) this is verified by laboratory findings whenever the sanitary survey indicates the need. Shellfish may be taken from such areas for direct marketing.

Satisfactory compliance.—This item will be satisfied when the three following criteria are met:

a. The area is not so contaminated with fecal material that consumption of the shellfish might be hazardous, and

b. The area is not so contaminated with radionuclides or industrial wastes that consumption of the shellfish might be hazardous (see section C, item 7, regarding toxins in shellfish growing areas), and

c. The coliform median MPN of the water does not exceed 70 per 100 ml., and not more than 10 percent of the samples ordinarily exceed an MPN of 230 per 100 ml. for a 5-tube decimal dilution test (or 330 per 100 ml., where the 3-tube decimal dilution test is used) in those portions of the area most probably exposed to fecal contamination during the most unfavorable hydrographic and pollution conditions. (Note: This concentration might be exceeded if less than 8 million cubic feet of a coliform-free dilution water are available for each population equivalent (*coliform*) of sewage reaching the area). The foregoing limits need not be applied if it can be shown by detailed study that the coliforms are not of direct fecal origin and do not indicate a public health hazard (*19*) (*20*).[8]

Public-health explanation.—A review of epidemiological investigations of disease outbreaks attributable to the consumption of raw shellfish reveals that two general situations prevail[9] insofar as pollution of growing or storage areas are concerned.

(1) Gross sewage contamination of a growing or wet storage area. (A report of a 1910 outbreak of typhoid fever involving 41 persons notes that raw sewage from a city with a population of 30,000 was discharged only a few hundred feet away from clam beds and floats (*27*) (*28*). In 1947 a case of typhoid fever was attributed to clams harvested 200 yards from the outlet of a municipal sewage treatment plant (*29*). In the latter case, the coliform MPN of the harbor water exceeded 12,000 per 100 ml. and the area had been posted as closed to shellfish harvesting.)

(2) Chance contamination of a growing or wet storage area by fresh fecal material which may not be diffused throughout the entire area (*14*) (*16*) (*17*) (*19*) and therefore not readily detectable by ordinary bacteriological procedures. The possibility of chance contamination was noted by Dr. Gurion in his report on a 1902 typhoid outbreak, and who is quoted in Public Health Bulletin No. 86, as "there is a zone of pollution established by the mere fact of the existence of a populated city upon the banks of a stream or tidal estuary which makes the laying down of oysters and clams in these waters a pernicious custom if persisted in, because it renders these articles of food dangerous at times, and always suspicious". The 1956 outbreak of infectious hepatitis in Sweden (691 cases) attributed to oysters which were contaminated in a wet storage area is an example of such contamination (*16*). Similarly in 1939, 87 cases of typhoid were attributed to fecal contamination of a storage area by a typhoid carrier (*14*).

It is well established that shellfish from water having a median coliform MPN not exceeding 70 per 100 ml.[8] *and which is also protected against chance contamination with fecal material*, will not be involved in the spread of disease which can be attributed to initial contamination of the shellfish. This is not surprising since a water MPN of 70/100 ml. is equivalent to a dilution ratio of about 8 million cubic feet of coliform-free water per day for the fecal material from each person contributing sewage to the area. This tremendous volume of water is available in shellfish growing areas through

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[8] This MPN value is based on a typical ratio of coliforms to pathogens and would not be applicable to any situation in which an abnormally large number of pathogens might be present. Consideration must also be given to the possible presence of industrial or agricultural wastes in which there is an atypical coliform to pathogen ratio (*30*).

[9] There is a third general consideration in which shellfish may be contaminated through mishandling. This is not related to growing area sanitation and is considered in part II of this manual.

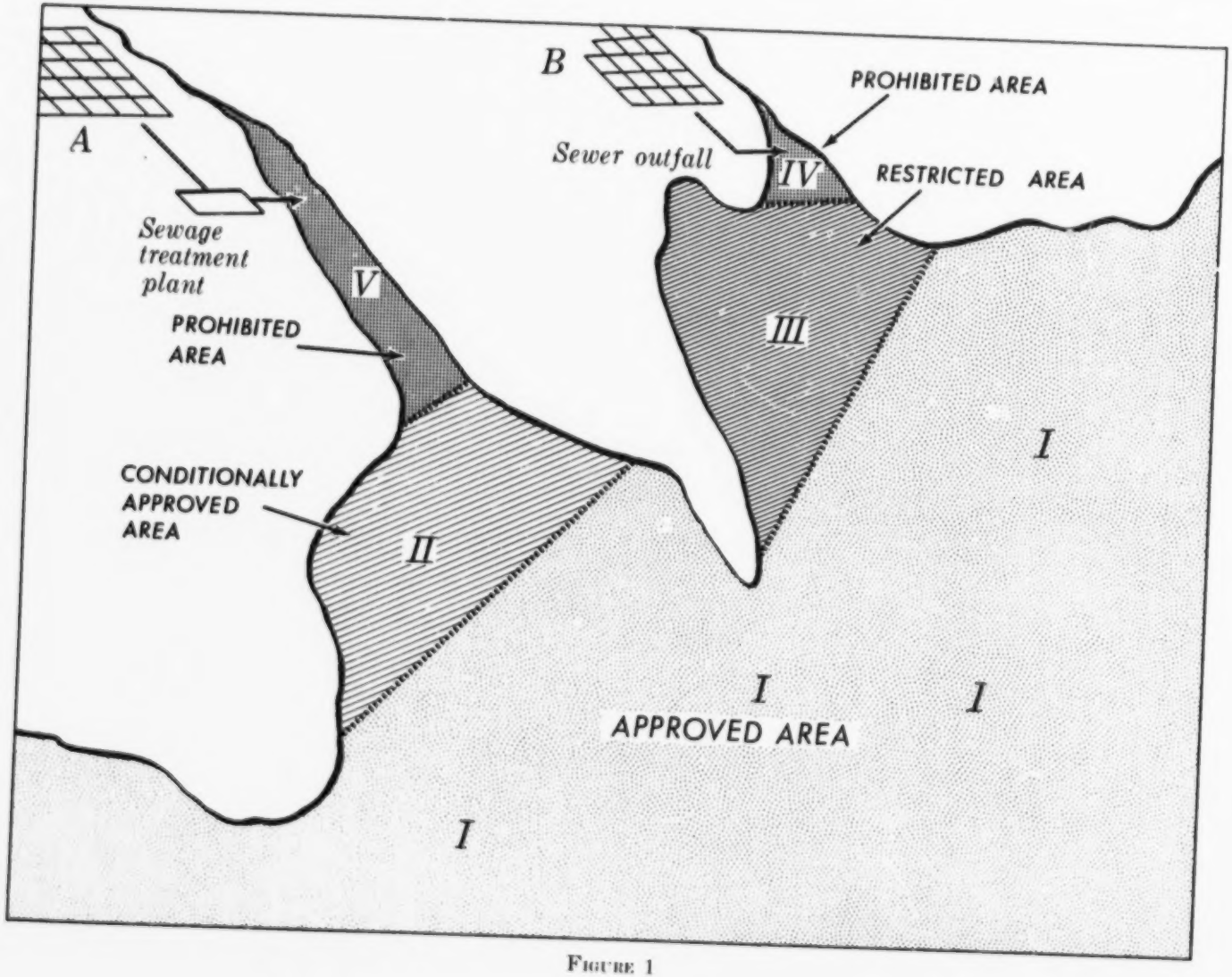
A
B
Sewage treatment plant
Sewer outfall
PROHIBITED AREA
RESTRICTED AREA
PROHIBITED AREA
CONDITIONALLY APPROVED AREA
APPROVED AREA
I
II
III
IV
V

FIGURE 1

tidal action which is constantly bringing unpolluted water into the area.[8]

Areas which are approved for direct market harvesting of shellfish which will be eaten raw must necessarily meet one general test; i.e, sewage reaching the growing area must be so treated, diluted, or aged that it will be of negligible public-health significance. This implies an element of time and distance to permit the mixing of the sewage or fecal material with the very large volume of diluting water and for a major portion of the microorganisms to die out. Studies of the natural die-off of microorganisms in an unfavorable marine environment have been summarized by Greenberg (*22*).

The effectiveness of sewage treatment processes must be considered in evaluating the sanitary quality of a growing area since the bacterial and viral content of the effluent will be determined by the degree of treatment which is obtained (*2*) (*73*) (*74*) (*75*). The results of bacteriological sampling must also be correlated with sewage treatment plant operation, and evaluated in terms of the minimum treatment which can be expected with a realization of the possibility of malfunctioning, overloading, or poor operation.

The presence of radionuclides in growing area waters may also have public-health significance since shellfish, along with other marine organisms, have the ability to concentrate such materials (*31*) (*32*) (*33*) (*34*). The degree to which radioisotopes will be concentrated depends upon the species of shellfish and the specific radioisotope. For example, it has been reported that the Eastern oyster has a concentration factor of 17,000 for Zn^{65} whereas the concentration factor in soft tissues for Sr^{89} is approximately unity (*31*) (*33*). The distribution of the radioisotope in the shellfish and the biological half-life are also variable. Sources of radioactive materials include fall-out, industrial wastes, and nuclear reactors. Limiting maximum permissible concentrations of radioactive materials expressed in terms of specific radioisotopes and unidentified mixtures in water and food have been established (*35*) (*36*). The current standard should be consulted in evaluating the public-health significance of detected radioactivity in market shellfish.

The bacterial quality of active shellfish will ordinarily be directly proportional to the bacterial quality of the water in which they grew; however, considerable variation in individual determinations may be expected. The coliform MPN's of the shellfish usually exceed those of the overlying water because shellfish filter large quantities of water to obtain food, thereby concentrating the suspended bacteria. This relationship will depend upon the shellfish species, water temperature, presence of certain chemicals, and varying capabilities of the individual animals.

4. Conditionally Approved Areas.—The suitability of some areas for harvesting shellfish for direct marketing is dependent upon the attainment of an established performance standard by sewage treatment works discharging effluent, directly or indirectly, to the area. In other cases the sanitary quality of an area may be effected by seasonal population, or sporadic use of a dock or harbor facility. Such areas may be classified as *conditionally approved*.

State shellfish control agencies shall establish *conditionally approved* areas only when satisfied that (a) all necessary measures have been taken to insure that performance standards will be met, and (b) that precautions have been taken to assure that shellfish will not be marketed from the areas subsequent to any failure to meet the performance standards and before the shellfish can purify themselves of polluting microorganisms.

Satisfactory compliance.—This item will be satisfied when—

a. The water quality requirements for an *approved* area are met at all times while the area is approved as a source of shellfish for direct marketing.

b. An operating procedure for *each conditionally approved* area is developed jointly by the State shellfish control agency, local agencies, including those responsible for operation of sewerage systems, and the local shellfish industry. The operating procedure should be based on an evaluation of each of the potential sources of pollution which may affect the area. The procedure should establish performance standards, specify necessary safety devices and measures, and define inspection and check procedures. (These procedures are described in

See footnote 8 on page 13.

more detail in the following public-health explanation.)

c. A closed safety zone is established between the *conditionally approved* area and the source of pollution to give the State agency time to stop shellfish harvesting if performance standards are not met.

d. Boundaries of *conditionally approved* areas are so marked as to be readily identified by harvesters.

e. Critical sewerage system units are so designed, constructed, and maintained that the chances of failure to meet the established performance standards due to mechanical failure or overloading are minimized.

f. There is a complete understanding of the purpose of the *conditionally approved* classification by all parties concerned, including the shellfish industry. Successful functioning of the concept is dependent upon the wholehearted cooperation of all interested parties. If such cooperation is not assured the State should not approve the area for direct harvesting of market shellfish.

g. Any failure to meet the performance standards is immediately reported to the State shellfish control agency by telephone or messenger. In some instances States may find it desirable to delegate the authority for closing a *conditionally approved* area to a representative of the agency located in the immediate area.

h. The State immediately closes *conditionally approved* areas to shellfish harvesting following a report that the performance standards have not been met. The area shall remain closed until the performance standards can again be met plus a length of time sufficient for the shellfish to purify themselves so that they will not be a hazard to the public health. (See section D-4, "Relaying," for information on the length of time required for self-purification of shellfish.)

i. The State shellfish control agency makes at least two evaluations during the shellfish harvesting season of each *conditionally approved* area including inspection of each critical unit of the sewerage system to determine the general mechanical condition of the equipment, the accuracy of recording devices, and the accuracy of reporting by the operating agency.

j. It is discovered that failure to meet performance standards have not been reported by the operating agency, or if the performance standards are not met, the area will immediately revert to a *restricted* or *prohibited* classification.

k. All data relating to the operation of a *conditionally approved* area, including operation of sewerage systems, are maintained in a file by the State shellfish control agency.

Public-health explanation.—The *conditionally approved* classification is designed primarily to protect shellfish growing areas in which the water quality might undergo a significant adverse change within a short period of time.[10] The change might result from overloading or mechanical failure of a sewage treatment plant, or bypassing of sewage at a lift station.

Water quality in many growing areas in the more densely populated sections of the country is, to some degree, dependent upon the operation of sewage treatment plants. For example, the boundaries of an approved shellfish area might be determined during a period when a tributary sewage treatment plant is operating at a satisfactory level. If there is some interruption in treatment it follows that there will be some degradation in water quality in the growing area, which may justify a relocation of the boundaries. The degree of relocation would depend upon such items as the distance between the pollution source and the growing area, hydrography, the amount of dilution water, and the amount of pollution.

The concept is also applicable to other situations in which there may be a rapid or seasonal change in water quality. Examples of such situations include—

a. A growing area adjacent to a resort community. During the summer months the community might have a large population which might have an adverse effect on water quality. However, during the winter when there are few people in the community the water quality might improve sufficiently to allow approval of the area. In some States this is known as a seasonal closure.

b. A protected harbor in a sparsely settled area might provide anchorage for a fishing fleet

[10] A natural disaster may also cause many sewage treatment plants to be out of service for an extended period of time. The *conditionally approved* area concept is not ordinarily concerned with such emergency situations.

several months a year. When the fishing fleet is in, the harbor water would be of poor sanitary quality; however, during the remainder of the year the quality of the harbor water might be satisfactory. The area would be approved for shellfish harvesting only when the fishing fleet is not using the harbor.

c. The water quality in an area fluctuates with the discharge of a major river. During periods of high runoff the area is polluted because of decreased flow time in the river. However, during periods of low runoff the area might be of satisfactory quality and thus be approved for shellfish harvesting.

The establishment of *conditionally approved* areas might be considered whenever the potential for sewage contamination is such that the limiting water quality criteria for an *approved* area might be exceeded in less than one week due to a failure of sewage treatment, or other situations as described above.

The first step in determining whether an area should be placed in the *conditionally approved* classification is the evaluation of the potential sources of pollution in terms of their effect on water quality in the area. Potential sources of pollution include the following:

(1) Sewage treatment plants.

(*a*) Bypassing of all or part of sewage because of mechanical or power failure, hydraulic overloading, or treatment overloading.

(*b*) Reduced degree of treatment due to operational difficulties or inadequate plant.

(2) Sewage lift stations.

(*a*) Bypassing during periods of maximum flow due to inadequate capacity.

(*b*) Bypassing because of mechanical or power failure.

(3) Interceptor sewers or underwater outfalls.

(*a*) Exfiltration due to faulty construction.

(*b*) Leakage due to damage.

(4) Other sources of pollution.

(*a*) Sewage from merchant or naval vessels.

(*b*) Sewage from recreation use of area.

The second step in establishment of a *conditionally approved* area is the evaluation of each source of pollution in terms of the water quality standards to be maintained, and the formulation of performance standards for each installation having a significant effect on the sanitary quality of the area. Examples of performance standards might include:

(1) Bacteriological quality of effluent from sewage treatment plants. This might be stated in terms of chlorine residual if the bacteriological quality of the effluent can be positively related to chlorine residual. The following is an example of a performance standard (*37*): "The median coliform MPN, in any one month, shall not exceed 500 per 100 ml., based on not less than 16 composite samples per month, and not more than 10 percent of the samples shall have an MPN in excess of 10,000 per 100 ml. Determinations of the chlorine residual of the effluent should be made hourly and recorded in the permanent plant records."

(2) Total quantity of sewage which can be discharged from any given unit, or from a combination of units, without causing the basic water quality standards to be exceeded.

(3) Amount of shipping in the area and the amount of sewage which can be expected.

Design criteria which may be useful in formulating an opinion on the quantity of sewage which can be discharged into an area without exceeding the desired water quality standards include: Population equivalent (*coliform*) of sewage; predicted survival of coliform in sea water, effectiveness of chlorination, and the total quantity of clean dilution water in an area. Results of many studies on the survival of bacteria in sea water have been summarized in *An Investigation of the Efficacy of Submarine Outfall Disposal of Sewage and Sludge;* Publication No. 14, California State Water Pollution Control Board, 1956.

The mechanical equipment at critical sewage treatment or pumping units should be such that interruptions will be minimized. Wherever possible operations should be automatically recorded on charts. Examples of the requirements which might be imposed, depending upon the importance of the unit in terms of water quality, include:

(1) Ample capacity for storm flows. (Storm water should ordinarily be excluded from the sanitary system.)

(2) Standby equipment to insure that treatment or pumping will not be interrupted because of damage to a single unit or to power failure.

(3) Instrumentation of pumps and equipment to allow the regulatory agency to determine that performance standards have been met. Examples include:

(*a*) Recording scales to indicate rate of chlorine use. Chlorine flow can be integrated with hydraulic flow to establish a ratio.

(*b*) Liquid level recording gages in overflow channels of sewage treatment plants and wet wells of lift stations to indicate when overflow takes place. Charts should be dated and initialed by the operator. Gages should be calibrated so that discharge can be estimated.

(*c*) Automatic devices to warn of failure or malfunctioning at self-operated pumping stations or treatment plants.

(4) The effect of storm sewage can be calculated by multiplying the total estimated flow by the observed coliform content. The result can be expressed in terms of population equivalents (*coliform*).

Design and operation of equipment should be such that closure provisions should not have to be invoked more than once per year under ordinary circumstances.

A closed safety area should be interposed between the *conditionally approved* area and the source of pollution. The size of such area should be based on the total time it would take for the operating agency to detect a failure, notify the State shellfish control agency, and for the latter agency to stop shellfish harvesting. It is recommended that the area be of such size that the flow time through the safety area be at least twice that required for the notification process to become effective. Due consideration should be given to the possibility that closure actions might be necessary on holidays or at night.

The type of marking which will be required for *conditionally approved* areas will vary from State to State depending upon the legal requirements for closing an area.

The length of time a *conditionally approved* area should be closed following a temporary closure will depend upon several factors including the species of shellfish, water temperature, purification rates, presence of silt or other chemicals that might interfere with the physiological activity of the shellfish, and the degree of pollution of the area. (See section D–1 of this manual for additional information on the natural purification of shellfish.)

5. Restricted Areas.—An area may be classified as *restricted* when a sanitary survey indicates a limited degree of pollution which would make it unsafe to harvest the shellfish for direct marketing. Alternatively the States may classify such areas as prohibited. (See section C–6, this manual.) Shellfish from such areas may be marketed after purifying or relaying as provided for in section D.

Satisfactory compliance.—This item will be satisfied when the following water quality criteria are met in areas designated by States as *restricted*.[11] [12]

a. The area is so contaminated with fecal materials that direct consumption of the shellfish might be hazardous, and/or

b. The area is not so contaminated with radionuclides or industrial wastes that consumption of the shellfish might be hazardous, and/or

c. The coliform median MPN of the water does not exceed 700 per 100 ml, and not more than 10 percent of the samples exceed an MPN of 2,300 per 100 ml, in those portions of the areas most probably exposed to fecal contamination during the most unfavorable hydrographic and pollution conditions. (Note: this concentration might be exceeded if less than 800,000 cubic feet of a coliform-free dilution water are available for each population equivalent (*coliform*) of sewage reaching the area.)

d. Shellfish from *restricted* areas are not marketed without controlled purification or relaying.

Public-health explanation.—In many instances it is difficult to draw a clear line of demarcation between polluted and nonpolluted areas. In such instances the State may, at its

[11] It is not mandatory that States use this classification. Areas not meeting the approved classification may be closed to all harvesting for direct marketing.

[12] Routine sanitary surveys and reappraisals of restricted areas shall be made on the same frequency as for approved areas. (See section C–1.)

option, classify areas of intermediate sanitary quality as *restricted* and authorize the use of the shellfish for relaying, or controlled purification.

6. Prohibited Areas.—An area shall be classified *prohibited* if the sanitary survey indicates that dangerous numbers of pathogenic microorganisms might reach an area. The taking of shellfish from such areas for direct marketing shall be prohibited. Relaying or other salvage operations shall be carefully supervised to insure against polluted shellfish entering trade channels. Actual and potential growing areas which have not been subjected to sanitary surveys shall be automatically classified as *prohibited*.

Satisfactory compliance.—This item will be satisfied when:

a. An area is classified as *prohibited* if a sanitary survey indicates either of the following degrees of pollution:

(1) The area is contaminated with radionuclides or industrial wastes that consumption of the shellfish might be hazardous and/or

(2) The median coliform MPN of the water exceeds 700 per 100 ml. or more than 10 percent of the samples have a coliform MPN in excess of 2,300 per 100 ml. (Note: This concentration might be reached if less than 800,000 cubic feet of a coliform-free dilution water are available for each population equivalent (*coliform*) of sewage reaching the area.)

b. No market shellfish are taken from *prohibited* areas except by special permit as described in section D.

c. Coastal areas in which sanitary surveys have not been made shall be automatically classified as *prohibited*.

Public-health explanation.—The positive relationship between enteric disease and the eating of raw or partially cooked shellfish has been outlined in section C–1. Prevention of the interstate transport of shellfish containing sufficient numbers of pathogenic microorganisms to cause disease is a primary objective of the National Program. Therefore, areas containing dangerous concentrations of microorganisms of fecal origin, or areas which may be slightly contaminated with fresh fecal discharges, should not be approved as a source of shellfish for direct marketing.

7. Closure of Areas Due to Shellfish Toxins.—The State shellfish control agency shall regularly collect and assay representative samples of shellfish from growing areas where shellfish toxins are likely to occur. If the paralytic shellfish poison content reaches 80 micrograms per 100 grams of the edible portions of raw shellfish meat, the area shall be closed to the taking of the species of shellfish in which the poison has been found.[17] The harvesting of shellfish from such areas shall be controlled in accord with the recommendations of sections E–1 and E–2 of this manual.

The quarantine shall remain in effect until such time as the State shellfish control agency is convinced the poison content of the shellfish involved is below the quarantine level.[18]

Satisfactory compliance.—This item will be satisfied when—

a. The State shellfish control agency collects and assays representative samples of shellfish for the presence of toxins from each suspected growing area during the harvesting season. (See section B-2 for assay methods.)

b. A quarantine is imposed against the taking of shellfish when the concentration of paralytic shellfish poison equals or exceeds 80 micrograms per 100 grams of the edible portion of raw shellfish.

Public-health explanation.—In some areas paralytic poison is collected temporarily by bivalve shellfish from free-swimming, one-celled marine plants on which these shellfish feed. The plants flourish seasonally when water conditions are favorable.

Cases of paralytic poisoning, including several fatalities, resulting from poisonous shellfish have been reported from both the Atlantic and Pacific coasts. The minimum quantity of poison which will cause intoxication in a susceptible person is not known. Epidemiological investigations of paralytic shellfish poisoning in Canada have indicated 200 to 600 micrograms of poison will produce symptoms in susceptible

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[17] This value is based on the results of epidemiological investigations of outbreaks of paralytic shellfish poison in Canada in 1954 and 1957 (16) (19).

[18] The provisions of this item apply only to shellfish which will be marketed as a fresh or frozen product as properly controlled heat processing will reduce the poison content of the shellfish.

persons and a death has been attributed to the ingestion of a probable 480 micrograms of poison. Investigations indicate that lesser amounts of the poison have no deleterious effects on humans. Growing areas should be closed at a lower toxicity level to provide an adequate margin of safety since in many instances toxicity levels will change rapidly (*38*) (*39*). It has also been shown that the heat treatment afforded in ordinary canning processes reduces the poison content of raw shellfish considerably.

A review of literature and research dealing with the source of the poison, the occurrence and distribution of poisonous shellfish, physiology and toxicology, characteristics of the poison, and prevention and control of poisoning has been prepared (*40*).

In Gulf coast areas, toxicity in shellfish has been associated (*12*) (*76*) with Red Tide outbreaks caused by mass bloomings of the toxic dinoflagellate, *Gymnodinium breve*. Toxic symptons in mice suggest a type of *ciguatera* fish poisoning rather than symptoms of paralytic shellfish poisoning.

Section D

PREPARATION OF SHELLFISH FOR MARKETING

1. Relaying.—State shellfish control agencies may approve the intra- or interstate transplanting of market shellfish from restricted or prohibited areas to approved areas subject to certain limitations. All phases of the operation shall be under the immediate supervision of responsible State(s) shellfish control or patrol agency(s). A memorandum of understanding shall be developed between the agencies responsible for the control of interstate relaying operations. (Shellfish may be transplanted from an *approved* area to another like area at any time without restriction due to sanitary reasons.)

Satisfactory compliance.—This item will be satisfied when—

a. Shellfish are not relaid from *restricted* or *prohibited areas* to *approved areas* without written permission of the State shellfish control agency.

b. All relaying operations are under the *immediate* supervision of the State shellfish control or patrol agency. Supervision shall be such that no polluted shellfish are marketed before the end of the approved relaying period. The supervising officer shall be authorized and equipped to enforce the State regulations on relaying; shall actually supervise the harvesting, transport and relaying of shellfish; and shall patrol the *approved* area during the period that shellfish are undergoing the cleansing process. However, continuous supervision will not be necessary if relaying operations are carried out during a period when shellfish may not be marketed. A continuous record of water temperature, salinity, and any other critical variables must be maintained when it is known that the limiting values may be approached and when the minimum relaying periods are being used.

c. State permission to relay shellfish is given only to responsible persons; responsibility to be determined by the past record of the permit applicant.

d. Relaid shellfish are held in the *approved* area for a period of time sufficient to allow them to cleanse themselves of polluting bacteria. (The time required for purification will be determined by water temperature, salinity, initial bacteriological quality and species of shellfish.)

e. Relaid shellfish are not harvested without written permission from the State shellfish control agency.

f. Areas designated for relaid shellfish are so located and marked that they may be readily identified by the harvesters and so that shellfish in any adjacent *approved* area will not be contaminated. (This requirement applies only to relaying during the harvesting season.)

g. Shellfish are not relayed intra or interstate from restricted or prohibited areas to *approved* areas without written permission of the State(s) shellfish control agency(s). (If shellfish are relayed interstate, a memorandum of agreement shall be devloped outlining the control measures to be used.)

Public-health explanation.—Shellfish transplanted from a polluted to a clean environment will cleanse themselves of the polluting bacteria or viruses. This is a natural phenomenon resulting from the shellfish feeding processes. Bacteria or viruses in the body and shell cavity of the shellfish at the time of transplanting are either used as food or are ejected in feces or pseudofeces.

The length of time required for this cleansing process is influenced by many factors including original level of pollution, water temperature, presence of chemicals inhibitory to physiological activity of the shellfish, salinity, and varying capabilities of the individual animals. Advice on limiting water temperatures, either maxmum or minimum, should be obtained from local marine biologists.

Investigations by marine biologists have confirmed that the psysiological activities of the Eastern oyster (*Crassostrea virginica*) is reduced when the water temperature falls below a certain value. It has been found that the pumping rate of Eastern oysters is reduced at water temperatures below 50° F., and that most animals stop pumping at a water temperature of about 41° F. However, a few oysters show slight activity at temperatures approaching 32° F. (*41*) (*42*). This phenomenon was first noted by shellfish bacteriologists who found that East-

ern oysters harvested from polluted areas during cold weather had coliform contents comparable with those of oysters harvested from clean areas during warmer weather (*43*) (*44*) (*45*).

Gibbard *et al.* (*46*) investigating temperature-induced hibernation was unable to demonstrate coliforms in Eastern oysters within a few days after the water temperatures dropped to 32° F. The rapidity with which hibernating oysters become active when the water temperature rises above the threshold value was discussed by Wachter (*47*) in 1925 and was demonstrated by Gibbard *et al.* (*46*). The latter investigator found that contamination accompanying a sudden two degree increase in water temperature from 41° to 43° F. was reflected in the oysters in one day.

Relaying operations must be carefully supervised by an official State agency since the shellfish may contain pathogenic microorganisms. Control must apply to all phases of the operation including initial harvesting, transportation, replanting, purification period, and final harvesting for marketing if the relaying area is adjacent to a restricted area or to an area containing relaid shellfish which have not been released for harvesting.

2. Controlled Purification.—Shellfish from *restricted* or *prohibited* areas may be marketed after effective controlled purification. Purification shall be permitted only under the immediate supervision of the State shellfish control agency. Water used for purification shall be of high bacteriological quality and its physical and chemical properties shall be favorable to maximum physiological activity of the shellfish. Stringent precautions shall be taken by the State shellfish control agency to insure that shellfish harvested from *restricted* or *prohibited* areas are actually submitted to an effective purification process before marketing.

Purification of shellfish from *prohibited* areas shall not be approved by the State unless relaying is not practical for biological reasons, and no public-health hazard will result from the use of such shellfish.

Satisfactory compliance.—This item will be satisfied when:

a. The controlled purification system, including water treatment, has been demonstrated to be consistently effective for the species of shellfish being purified. Purification may be accomplished in either a natural body of water or in tanks. (In determining the effectiveness of the process at least the following factors shall be investigated: Water temperature, silt or turbidity, dissolved oxygen, presence of chemicals, and time required for purification.) The bacteriological quality of the purified shellfish shall be at least equal to shellfish of the same species harvested from local *approved* areas.

b. A purification plant operating procedure is developed and copies are supplied to the Public Health Service.

c. Water used for purification is obtained from an area meeting the physical and bacteriological requirements of an *approved* growing area, or in the case of treated water the bacteriological limits of the Public Health Service Drinking Water Standards (*48*) are met. If water is to be treated, it shall be obtained from an area meeting at least the sanitary requirements for a *restricted* area.

d. Water used for purification has chemical and physical characteristics conducive to maximum physiological activity of the shellfish. (Consideration shall be given to the following: Presence of chemicals, turbidity, temperature, salinity and dissolved oxygen, and to the adequacy of the facilities of the operating agency for measuring these characteristics.)

e. Shellfish are freed of contamination and foreign material adhering to shells before purification.

f. Shellfish are culled before and after purification.

g. Purification plant operation is under the administrative control of the State shellfish control agency. Purification plants may be operated by agencies other than the State; however, insofar as the National Shellfish Sanitation Program is concerned, the State is responsible for satisfactory operation.

h. Laboratory control is maintained over the purification operation. Controls shall include at least the following: Daily or tidal-cycle bacteriological quality of water; final bacteriological quality for each lot of shellfish purified; and, when they are critical factors, hourly or continuous salinity determinations and tidal-cycle turbidity determinations.

i. The plant operator possesses a satisfactory knowledge of the principles of water treatment and bacteriology.

j. Animals, rodents, and unauthorized persons are excluded from the plant.

k. Plant employees fulfill the qualifications for a shucker as described in section B–28, part II of this manual.

l. The State has an effective system for assuring that shellfish harvested from *restricted* areas will be submitted to purification before marketing. Shellfish harvesting from *prohibited* areas for controlled purification shall be under the immediate supervision of the State.

m. Shellfish from *prohibited* areas are not subjected to purification unless the State shellfish control agency can show that relaying or depletion is not biologically feasible; and that no public-health hazard will result from the use of such shellfish.

Public-health explanation.—The ability of shellfish to purify themselves in clean water was discovered early in the 1900's. The biological process is reasonably well understood and is described by Arcisz and Kelly (*26*) as follows:

"Purification is a mechanical process effected by the physiological functioning of the shellfish in clean water. When shellfish are feeding, the gills act as a filter to strain out some of the material that may be brought in by the water which passes through them. If this water contains sewage, some of the microorganisms in it are entrapped in the mucus on the body of the shellfish and transferred to the alimentary tract. Some of these are perhaps utilized as food (*49*) and the others discharged from the body in the form of feces and pseudofeces. When shellfish from polluted water are placed in clean water, the sewage bacteria are eliminated from the shellfish, and, since no more are ingested, purification is accomplished."

The purification process has been investigated extensively in England and to a lesser extent in the United States and Canada (*50*) (*51*) (*52*). The technique is reliable if proper methods are used, and insofar as is known, is applicable to all commercial species of shellfish.

Many of the earlier investigators suggested that purification be accomplished in tanks using water which had been subjected to a treatment process (*52*). The analogy with water treatment was carried to the point of recommending a chlorine residual in the purification tanks. However, fishery biologists have shown that shellfish pumping is decreased or inhibited by even small quantities of chlorine (*53*) (*54*). The inhibitory effect of chlorinated-dechlorinated water on activity of Eastern oysters has been noted by the Public Health Service Shellfish Sanitation Laboratory.

Since purification depends upon the pumping rate of the shellfish, it is important that the water be free of chemicals or physical characteristics which might interfere with this activity. For example, silt or dissolved organic substances may influence the pumping rates of shellfish (*55*) (*56*). The relationship of water temperature to pumping rates has been mentioned previously.

Shellfish purification facilities have generally been considered to include holding tanks and water treatment facilities (*57*) (*58*); however, investigations in Canada and England have demonstrated that purification can be accomplished with relatively simple installations if the operation is supervised properly (*59*) (*50*) (*60*) (*61*). Accordingly, any purification process of *proven* effectiveness will be accepted by the national program.

Administrative control of the purification process is necessary to insure that shellfish are properly washed and culled, are held for the required length of time, and that the purification water supply is properly controlled.

Section E

CONTROL OF HARVESTING FROM CLOSED AREAS

1. Identification of Closed Areas.—Shellfish harvesters shall be notified by direct notice and warning signs of areas closed to harvesting. Closed areas shall be so marked or described that they may be easily recognized by the harvesters. The measures necessary to accomplish delineation and notification will vary with the structure of the local shellfish industry and with the legal requirements of each State.

Satisfactory compliance.—This item will be satisfied when:

a. The boundaries of the closed areas are marked by fixed objects or landmarks in a manner which permits successful prosecution of any violations of the closed areas.

b. Shellfish harvesters are notified of the location of closed areas by publication or direct notification (such as registered mail) and/or warning signs posted at points of access to each closed area. The method of notification and identification should permit the successful prosecution of persons harvesting shellfish from the closed areas. (The limiting of shellfish harvesting permits to specific areas is an alternative to posting or notification. Where such a system is used, posting will be required only for closed areas which contain market shellfish.)

Public-health explanation.—Previous sections of this manual have described the public-health reasons for limiting shellfish harvesting to areas free of contamination and shellfish toxins. Methods have been described for the evaluation and classification of such areas. However, classification is not effective unless the State can prevent illegal harvesting of shellfish for direct marketing from these closed areas.

For the most part, control of illegal harvesting depends upon the police activities as described in section E-2. However, adequate delineation of the closed areas is fundamental to effective patrol.

The type of area identification will be determined by the structure of the local shellfish industry. Posting a warning sign is one method of informing shellfish harvesters that an area is closed to the taking of shellfish for public-health reasons. However, if the local shellfish industry is highly organized, with shellfish being harvested by only a few operators, identification may be accomplished by officially informing the harvesters that certain areas are closed to the taking of shellfish. It is recommended that the advice of the State's legal counsel be obtained to insure that the marking of closed areas and notifications to shellfish harvesters are such that illegal harvesting can be prosecuted successfully.

2. Prevention of Illegal Harvesting of Shellfish From Closed Areas.—Closed growing areas shall be patrolled by a State agency to prevent illegal harvesting. The patrol force shall be so equipped that its officers will be able to apprehend persons taking shellfish from closed areas.

Satisfactory compliance.—This item will be satisfied when—

a. There is no evidence that shellfish are being harvested from closed areas except by special permit as required to meet local conditions.

b. Closed shellfish growing areas are patrolled by representatives of an official agency, due consideration being given to night, weekend and holiday patrols. (States may delegate patrol activities to local organizations; however, responsibility for effective control will remain with the State insofar as the National Program is concerned.

c. Patrol forces are so equipped that persons observed in closed areas may be apprehended.

d. Complete records of patrol activities, including violations and court actions, are maintained in the central office of the State shellfish control or patrol agency. It will be the responsibility of the State to include local patrol activities in these records. (See section A, subsection 2(e) regarding monthly summaries of patrol activities.)

Public-health explanation.—The primary objective of the National Program is to insure that shellfish will be harvested only from areas which are free of dangerous concentrations of

pathogenic microorganisms, industrial or radioactive wastes, pesticides or shellfish toxins.

Growing areas may be classified as to their public-health suitability for shellfish harvesting on the basis of information obtained by sanitary and toxicological surveys. However, if local shellfish harvesters are not convinced of the need for restrictions, shellfish may be harvested surreptitiously from the closed areas. Thus, patrol failure may nullify the public-health safeguards resulting from sanitary survey activities.

The fact that law prohibits the removal of shellfish from certain areas will deter most persons from attempting to harvest such shellfish provided they are aware of the law and of the areas which are closed. However, local public opinion may not support the need for such closures. In such cases favorable opinion can probably be developed only through an educational program or a locally demonstrated need such as an epidemic or outbreak of paralytic shellfish poisoning. There is also a minority element not concerned with the welfare of their customers and who, through ignorance or purpose, will attempt to circumvent the harvesting restrictions.

Patrols must, therefore, be directed against three classes of individuals; i.e., those who are ignorant of the law, those who believe the law is unjust or unreasonable, and those who have no regard for the law.

Several mechanisms for improving the effectiveness of patrols include educational programs to acquaint shellfish harvesters with the public-health reasons for the closures, elimination of the "temptation element" by depletion, and relaying or purification. Apprehension, prosecution, and punishment of violators is a final resort.

The type of patrol organization needed for any particular situation cannot be specified and is determined by the nature of areas to be patrolled, means of access, methods of harvesting, and species. Patrol equipment should be such that the officers can apprehend persons harvesting shellfish in a closed area. Necessary equipment might include patrol boats capable of operating in open waters; small, high-speed, readily transportable boats, or patrol automobiles. In many instances, two-way radio will be helpful in coordinating patrol activities. Radar surveillance systems might also be of assistance, particularly during foggy weather or at night.

Organization of the patrol activity must take into consideration the need for night, weekend, holiday, and surprise patrols. Either nuisance or continual patrol may be used depending on the nature of the area to be patrolled and the type of industry.

The adequacy of State laws as a basis for prosecution is an important component of this activity. Shellfish patrol will probably be ineffective if State laws are so written or interpreted that violators cannot be successfully prosecuted, or if penalties are so small that they are economically unimportant. The latter point may be important in an area where local public opinion does not support the need for the restriction.

3. Depletion of Closed Areas.—The State shellfish control or patrol agency shall supervise all depletion operations. All market-size shellfish and as many of the smaller size as can be gathered by reasonable methods shall be removed in the initial depletion operation. Depletion of each area shall be carried out at intervals to prevent the development of market-sized shellfish.

Satisfactory compliance.—This item will be satisfied when—

a. The State shellfish control or patrol agency exercises direct supervision over each depletion project including patrol of the area in which the shellfish are relaid. (See section D–1.)

b. All market shellfish and as many of the smaller size shellfish as can be gathered by reasonable methods are removed in the depletion operation.

c. Similar supervised depletion operations are carried out at intervals to prevent development of market-sized shellfish in quantities which would make commercial harvesting economically practicable in the depleted areas.

Public-health explanation.—Complete removal of shellfish from polluted to clean areas under appropriate precautions is the best safeguard against contaminated shellfish reaching the market. In some cases depletion may be more economical and effective than patrol of closed areas.

Appendix A

BACTERIOLOGICAL CRITERIA FOR SHUCKED OYSTERS AT THE WHOLESALE MARKET LEVEL

The development of satisfactory bacteriological criteria for interstate shipments of oysters as received at the wholesale market level has been under consideration since 1950. At that time the Canadian Department of National Health and Welfare pointed out that most of the U.S.-shucked Eastern oysters sold in Canada had high coliform MPN's, high standard plate counts, or both (*2*). The Canadian experience with market standards for oysters was discussed at the 1956 National Shellfish Sanitation Workshop (*2*) and the Workshop adopted on an interim basis the following bacteriological standard for shucked Eastern oysters at the wholesale market level:

"*Class 1, Acceptable:* Shucked oysters with a Most Probable Number (MPN) of coliform bacteria of not more than 16,000 per 100 ml., and/or a Standard Plate Count of not more than 50,000 per ml.

"*Class 2, Acceptable on Condition:* Shucked oysters with a coliform MPN greater than 16,000 per 100 ml., but less than 160,000 per ml., and/or a Standard Plate Count greater than 50,000 per ml., but less than 1 million per ml. (The oysters will be accepted on the condition that the shellfish sanitation authority in the originating State will make immediate investigation of the producer's plant and operations and will submit a report of such investigations to the control agency in the market area. On the basis of this report the control agency in the market will reject or permit further shipments from the producer in question.)

"*Class 3, Rejectable:* Shucked oysters with a coliform MPN of 160,000 or more per 100 ml., and/or a Standard Plate Count of 1 million or more per ml."

In establishing the above interim standards, the 1956 Workshop recognized the limitations of the coliform group as an index of quality in that it failed to reveal whether the shellfish had been harvested from polluted areas or had been exposed to contamination during handling and processing subsequent to removal from the water. A recommendation was made that investigations be conducted to evaluate the significance of other bacterial indices. The fecal coliform group was suggested as a possible substitute for the coliform indices.

In partial fulfillment of this suggestion, a report on an interstate cooperative study to evaluate bacteriological criteria for market oysters was presented at the 1958 Shellfish Sanitation Workshop (*3*). A feature of this report was the development and evaluation of a method for the estimation of fecal coliform organisms following a procedure originally developed by Hajna and Perry (*77*). Gross increases in coliform organisms were observed during normal acceptable commercial practices. The magnitude of changes in coliform organisms was of the same order as those observed in plate counts. The results clearly demonstrated the inadequacy of the coliform group as an indicator of the sanitary quality of shellfish. It was further concluded that the plate count was of equal significance in revealing chance contamination or violations of acceptable storage time and temperature. On the other hand, the results of the examinations for fecal coliform organisms revealed a much higher degree of stability as the shellfish proceeded through commercial channels and thus suggested the greater suitability of this parameter as an index of sanitary quality at the wholesale market level. After due consideration of the report, the 1958 Workshop changed the interim bacteriological standard

for fresh and frozen shucked oysters at the wholesale market level to the following:

Satisfactory.[15] *E. coli* density of not more than 78 MPN per 100 ml. of samples as indicated by production of gas in E. C. liquid broth media nor more than 100,000 total bacteria per ml. on agar at 35° C. will be acceptable without question. An *E. coli* content of 79 to 230 MPN per 100 ml. of sample or a total bacteria count of 100,000 to 500,000 per ml. will be acceptable in occasional samples. If these concentrations are found in two successive samples from the same packer or repacker, the State regulatory authority at the source will be requested to supply information to the receiving State concerning the status of operation of this packer or repacker.

Unsatisfactory.[15] *E. coli* content of more than 230 MPN per 100 ml. of sample or a total bacteria count of more than 500,000 per ml. will constitute an unsatisfactory sample and may be subject to rejection by the State shellfish regulatory authority. Future shipments to receiving markets by the shipper concerned will depend upon satisfactory operational reports by the shellfish regulatory authorities at the point of origin.

In adopting the above standards, the 1958 Workshop recommended that the cooperative studies conducted by city and State laboratories and the Public Health Service be continued.

The 1961 Workshop reviewed still more data collected by the collaborating agencies during the 1958–61 period (*67*) and after considerable deliberation agreed to continued use of the interim bacteriological standards arrived at by the 1958 Workshop.

The 1964 Workhop considered all bacteriological data available up to that time (Nov. 17–19), including data relative to *Crassostrea gigas*, and adopted the following standards on a permanent basis, versus the previous interim basis, as being applicable to all species of fresh and frozen oysters at the wholesale market level, *provided they can be identified as having been produced under the general sanitary controls of the National Shellfish Sanitation Program.*[16]

Satisfactory. Fecal coliform density[17] of not more than 230 MPN per 100 grams and 35° C. plate count[18] of not more than 500,000 per gram will be acceptable without question.

Conditional. Fecal coliform density of more than 230 MPN per 100 grams and/or 35° C. plate count of more than 500,000 per gram will constitute a conditional sample and may be subject to rejection by the State shellfish regulatory authority. If these concentrations are found in two successive samples from the same shipper, the State regulatory authority at the source will be requested to supply information to the receiving State concerning the status of operation of this shipper. Future shipments to receiving markets by the shipper concerned will depend upon satisfactory operational reports by the shellfish regulatory authorities at the point of origin.

In establishing the above bacteriological standards the 1964 Workshop took cognizance of the fact that no known health hazard was involved in consuming oysters meeting the standard; that oysters produced in the Gulf Coast States with warmer growing waters, could meet the standard if harvested, processed, and distributed according to the National Shellfish Sanitation Program requirements, and that the oysters harvested were from "approved" growing areas complying with the standards for growing areas established in part I of the PHS Publication No. 33.

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[15] *E. coli* was defined as coliforms which will produce gas from E. C. medium within 48 hours at 44.5° C. in a water bath will be referred to as fecal coliforms.

[16] The standards are not considered meaningful in the absence of such information.

[17] Fecal coliform organisms are those which, on transfer to E.C. medium from gas positive presumptive broth tubes show production of gas after incubation in a water bath at 44.5° C. ±0.2° C. for 24 hours. Where air incubation is at 45.5° C. ±0.2° C. comparative tests must be made to determine comparable time of incubation.

[18] Plate count is the number of bacteria determined by the "Standard Plate Count: procedure for shellfish described in the APHA Recommended Procedures for the Bacteriological Examination of Sea Water and Shellfish."

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